DEPARTMENT OF HEALTH AND HUMAN SERVICES

M29397

Food and Drug Administration
New Jersey District Office
Central Region
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Parsippany, NJ 07054
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WARNING LETTER

Certified Mail
Return Receipt Requested

File: 99-NWJ-35

September 3, 1999

Thomas Pizio
President
Absolute Fire Protection Company, Inc.
2800 Hamilton Boulevard
South Plainfield, NJ 07080

Dear Mr. Pizio:

During the August 24-25, 1999 inspection of your oxygen repackaging facility, our investigator documented deviations from Current Good Manufacturing Practices for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, Part 211). These deviations cause your drug product, Oxygen, USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act.

Those deviations included:

- Failure to perform identity and purity testing on Oxygen, USP transfilled from industrial sized cylinders to smaller cylinders. *[21 CFR 211.165].*

- Failure to test each lot or cylinder of Oxygen, USP received to determine conformance with appropriate specifications for identity and strength *[21 CFR 211.84(d)(2)].* Specifically, you do not obtain or maintain certificates of analysis indicating the identity and purity of the Oxygen, USP you receive from your supplier, Compressed Gas Inc., Lodi, New Jersey. Also, in lieu of the previous, your firm's employees do not witness Compressed Gas Inc. performing identity and purity testing.

- The device used to test incoming oxygen to be transfilled is inadequate for the task of determining the purity of the Oxygen, USP you transfill *[21 CFR 211.160(b)(1)].* The device has an accuracy of +/- 2%, whereas Oxygen, USP has a minimum purity of 99.0%. In addition, you cannot demonstrate equivalency or superiority to the USP procedure, to which quality your transfilled oxygen product purports to have *[21 CFR 211.160(b)(3)].*

- Failure to perform transfilling to temperature and pressure specifications and the subsequent recording of the temperature and pressure filled to [21 CFR 211.110(a)]. The use of the cylinder temperature should have been incorporated into your batch records and the appropriate temperature/pressure combination recorded. Also, the practice of immersing cylinders in cold water while filling is inadequate and may be dangerous.

- Persons performing oxygen transfilling operations and management overseeing the oxygen transfilling operation have no training in Current Good Manufacturing Practices for Finished Pharmaceuticals *[21 CFR 25 (a) & (b)]*. In addition, the training records do not indicate any schedule or frequency for update training for employees.

- Failure to maintain documentation of the performance of in-process cylinder tests, including leak test, venting, blowing down, or evacuation/vacuum. *[21 CFR 211.110(a)]*.

- Failure to generate a master procedure describing your transfilling operation *[21 CFR 211.186]*.

- Batch production records are not reviewed by a person or persons acting as the quality unit for your firm *[21 CFR 211.192]*.

- Standard operating procedures for complaint and recall activities bear no approval signature or date and no quality review and approval signature or date. Standard operating procedures for transfilling activities bear no quality review and approval signature and date *[21 CFR 211.100(a)]*.

- Documentation of Oxygen, USP label reconciliation is not being performed *[21 CFR 211.125(c)]*.

The above deviations are not intended to be an all-inclusive list of violations. As a repackager of drug products for human use, you are responsible for assuring that your overall operation and the product you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and /or injunction.

You should notify this office in writing within 15 working days upon receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

By copy of this letter, we are advising the U.S. Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Food, Drug and Cosmetic Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

Your reply should be directed to the Food and Drug Administration, Attention: Kirk D. Sooter, Compliance Officer, at the address and telephone number above.

Sincerely yours,

Douglas I. Ellsworth
District Director

Cc: Beneficiary Services and Providers Branch Chief for New Jersey
U.S. Health Care Financing Administration
Region II
26 Federal Plaza, Room 3811
New York, NY 10278-0063